

U.S.S.N. 10/054,171  
Filed: January 17, 2002  
AMENDMENT AND RESPONSE TO OFFICE ACTION

### Amendment

#### In the Claims

1. (currently amended) A method of detecting osteoporosis in a ~~mammalian individual to be tested~~ comprising:
  - a) obtaining a sample of a bone related tissue or cells; and
  - b) ~~measuring assaying~~ the concentration of at least one marker selected from the group consisting of infectious agents, a factor produced by an infectious agent ~~produced factors~~, and heat shock proteins (HSPs) produced in response to an infectious agent, and
  - c) comparing the concentration of the at least one marker with the concentration of the marker in a sample of the same bone related tissue or cells from a control individual who does not have osteoporosis.
2. (currently amended) The method of claim 1 further comprising comparing the concentration of a first ~~assay~~ marker with concentrations of ~~a second or more assays~~ same marker obtained from the same individual over a period of time ~~or against a standard concentration.~~
3. (currently amended) The method of claim 1 wherein the marker is a HSP and the bone related tissue or cells are obtained under conditions that do not induce a change in the amount of one or more HSPs ~~response in the mammalian subject tissue or cells.~~
4. (original) The method of claim 3 wherein the HSP is selected from the group consisting of HSP 70, HSP 60, HSP 90, gp 96, cpn10, cpn20, ubiquitin, and cpn 30.

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5. (original) The method of claim 2 wherein the time period between the first assay and the second assay is at least about 12 hours.
6. (original) The method of claim 1 wherein the sample comprises bone cells or body fluid.
7. (original) The method of claim 3 wherein the HSP is HSP 60.
8. (original) The method of claim 3 wherein the HSP is HSP 70.
9. (original) The method of claim 3 wherein the HSP is ubiquitin.
10. (original) The method of claim 3 wherein the concentration of HSP is measured using an immunoassay.
11. (original) The method of claim 3 wherein the concentration of HSP is measured using an assay for a nucleotide molecule encoding HSP.
12. (currently amended) The method of claim 1 wherein the ~~pathogen~~ infectious agent is selected from the group consisting of bacteria, viruses, protozoa, parasites and fungi.
13. (currently amended) The method of claim 1 wherein the ~~pathogen~~ infectious agent is selected from the group consisting of bacterial produced factors, viral produced factors, protozoal produced factors, parasitic produced factors and fungal produced factors.
14. (original) The method of claim 12 wherein the bacteria is selected from the group consisting of *Staphylococcus aureus*, *Porphyromonas gingivallis*, *Eikenella corrodens*, *Actinobacillus actinomycetemcomitans*, *Prevotella intermedia*, *Campylobacter rectus*, *Staphylococcus epidermidis*, *Salmonella spp.*, *Escherichia coli*, *Neisseria gonorrhoea*, *Neisseria*

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*meningitis, Mycobacterial tuberculosis, Haemophilus influenzae, Pasteurella multocida, B. bronchiseptica, and Fusobacterium nucleatum.*

15. (currently amended) The method of claim 1 wherein the ~~pathogen~~ infectious agent is a ~~bacteria~~ bacterially produced factor selected from the group consisting of endotoxin-LPS, gapstatin, and dermonecrotic toxin (DNT).

16. (original) The method of claim 15 wherein the factor is selected from the group consisting of gapstatin and dermonecrotic toxin.

17. (original) The method of claim 15 wherein the factor is gapstatin.

18. (original) The method of claim 15 wherein the factor is dermonecrotic toxin.

19. (original) The method of claim 14 wherein the bacteria is selected from the group consisting of *Staphylococcus aureus*, *Actinobacillus actinomycetemcomitans*, *Bordetella bronchiseptica*, and *Fusobacterium nucleatum*.

20. (cancelled) A method of treating or preventing osteoporosis caused by an infectious agent, an infectious agent produced factor, or a bone disease comprising administering to a mammalian subject a therapeutically effective amount of a formulation selected from the group consisting of an HSP antigenic formulation and an infectious agent antigenic formulation.

21. (cancelled) The method of claim 20 wherein the bone disease is induced by bone infectious agents selected from the group consisting of viruses, bacteria, fungi, protozoa and parasites.

22. (cancelled) The method of claim 20 wherein the HSP is complexed with an antigenic material or formulated in combination with an adjuvant.

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23. (cancelled) The method of claim 20 wherein the antigenic material is a peptide or a protein having an antigenic determinant of a virus, bacteria, fungi, protozoa or parasite that induces a bone disease.

24. (cancelled) The method of claim 21 wherein the antigenic material includes an antigenic determinant of a virus selected from the group consisting of immunodeficiency virus type I (HIV-I), human immunodeficiency virus type II (HIV-II), hepatitis type A, hepatitis type B, hepatitis type C, influenza, Varicella, adenovirus, herpes simplex type I (HSV-I), herpes simplex type II (HSV-II), rinderpest, rhinovirus, echovirus, rotavirus, respiratory syncytial virus, papilloma virus, papova virus, cytomegalovirus, echinovirus, arbovirus, huntavirus, coxsackie virus, mumps virus, measles virus, rubella virus and polio virus.

25. (cancelled) The method of claim 20 wherein the HSP is selected from the group consisting of HSP 60, HSP 70, HSP 90, gp 96, cpn 10, cpn 20, ubiquitin, cpn 30, and combinations thereof.

26. (cancelled) The method of claim 20 wherein the osteoporosis is osteopenia.

27. (cancelled) The method of claim 20 wherein the osteoporosis is caused by a bacteria or a bacteria produced factor.

28. (cancelled) A kit for use in the method of claim 1.

29. (cancelled) A pharmaceutically acceptable composition for administration to a patient for use in the method of claim 20.